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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,050

02/20/2002

David W. Osborne

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,050	Applicant(s) OSBORNE, DAVID W.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-22,25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-22,25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12-5-07 has been entered.

Amendment and remarks of 12-5-07 is acknowledged.

Claims 1, 4, 7-22, 25 and 27-31 are pending. Claims 27-29 have been added by the amendment dated 11-2-07 and Claims 30-31 have been added by the amendment dated 12-5-07.

The following is a new rejection:

Claim Rejections - 35 USC § 112

2. Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim 27 recites that dapsona is applied no more than once a day, which is not supported by the instant specification. A review of the instant disclosure only reveals that dapsona may be applied as once a day or more (page 10, last line of

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first paragraph) but nowhere states that the administration of dapsone should not be more than once a day. Claim 29 recites the limitation, “wherein the efficacy for treating non-inflammatory acne is inverse to the efficacy for treating inflammatory acne”, which is not supported by the specification because applicants nowhere (including the data in Table 1) mention the relationship between treating non-inflammatory acne and its effect on the number of inflammatory acne lesions. While applicants state on page 7 of their response dated 11-2-07 that the data of table 1 supports the inverse relationship, the specification does not clearly disclose to the skilled artisan that the inventors considered the inverse relationship to be part of their invention because other than the results on table 1 applicants have not described such a relationship and the newly added limitation is picked from the general disclosure. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). A skilled artisan reading the general disclosure of the instant applicants would not be able to readily conceive that the inverse relationship claimed is a part of the instant invention.

3. Claims 1, 4, 7-22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claims recite “A method of reducing a number of non-inflammatory lesions”, which is indefinite because the phrase “a number of non-inflammatory lesions” because it

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is not clear if the instant treatment is aimed at reducing a certain number of lesions.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 7, 13, 14, 20, 21, 25 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 ('085) to Osborne or US 5,863,560 ('560) to Osborne (as evidenced by Russell, AFP, 2000).

Instant claim 1 recites a method for reducing the number of non-inflammatory acne lesions comprising the step of topically applying a composition consists essentially of dapson. Claim 25 is directed to a method of treating non-inflammatory acne lesions comprising the step as in claim 1. '085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapson as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapson, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapson concentration. Both references disclose dapson in a topical composition and for

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the same purpose i.e., treatment of acne. Russell teaches that acne, usually diagnosed by the patient, is of three type i.e., inflammatory acne, non-inflammatory acne or a mixture of both (inflammatory and non-inflammatory) types and that the most common situation of acne is a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While '085 and '560 does not disclose treatment of non-inflammatory acne, nothing in the above references indicates that acne (treated by Dapsone of '085 or '560) is not the commonly occurred form (as taught by Russell) and that the acne lesions are only of inflammatory type.

New claims 27, 30 and 31 have been rejected under this section because, as explained above, both the references teach dapsone for treating acne, which according to Russell is usually a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While the references of Osborne do not state the extent of efficacy in treating non-inflammatory acne i.e., the ability to inhibit at least 45% and the inverse relationship in the efficacy of dapsone in treating inflammatory acne as opposed to non-inflammatory (claims 28 and 29) are inherent to the dapsone of '085 and '060. Further, non-inflammatory lesions are inherent to the acne described in the teachings of '085 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of '085 and '560.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21, 25 and 27-31 above, and further in view of US 6,200,964 to Singleton et al OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of in view of Russell and US 6,200,964 to Singleton et al.

7. '085 and '560 fail to teach the claimed cream, lotion, spray, suspension and ointment formulations. The above references also fail to teach 5% dapsons. Russell suggests preparation of acne treatment formulations in the form of a gel, ointment or cream depending on the patient's skin type (page 3).

8. '964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsons in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsons compositions of '085 or '560 in the form of a spray, lotion or a cream or an ointment, depending the type of the skin of the patient being treated because '964 teaches acne preparations in any of the above forms and Russell suggests

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creams are appropriate for dry skin, gels for oily skin, lotions for any skin type and solutions for dissolved topical antibiotics. Accordingly, it would have been within the scope of a skilled artisan to optimize the amount of dapsone (of '085 and '560) and choose the type of the formulation i.e., a gel or a lotion or a cream etc., depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions- both types).

Response to Arguments

9. Applicant's arguments filed 11-02-07 have been fully considered but they are not persuasive.

10. Applicants' arguments presented on 11-02-07 are similar to that presented on 5-10-07, with respect to the anticipation as well as obviousness rejections. Applicants' arguments have not been reproduced here because of their lengthy nature. Applicants are directed the arguments addressed the examiner (office action dated 10-17-07), all of which have been incorporated here by reference. Additionally, applicants state that the new claims 27-29 are not taught by Osborne. However, the rejection above explains how the new claims have been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone

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number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
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